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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,909	11/24/2003	Roland Janzen	DCS-9151	5291
34500	7590	10/18/2005	EXAMINER	
DADE BEHRING INC. LEGAL DEPARTMENT 1717 DEERFIELD ROAD DEERFIELD, IL 60015			VENCI, DAVID J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/720,909	JANZEN ET AL.
	Examiner David J. Venci	Art Unit 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on August 4, 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 17-21 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8, 12 and 14-16 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-12 and 14-21 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing-sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

Examiner acknowledges Applicants' reply, filed August 4, 2005. Currently, claims 1-8, 12 and 14-16 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

In claim 14, there is insufficient antecedent support for the recitation of "a second substrate having... regions capable of selectively binding first binding species associated with said first substrate."

The disclosure is further objected to for various informalities. Appropriate correction is required.

In Tables 1-6, the recitation of "Level" is indefinite because it is not clear what "Level" is measured or the exact quantity or unit of measurement of the various "Levels"

***Claim Rejections - 35 USC § 112***

Claims 1-8, 12 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 14, the recitation of "attached thereto" is indefinite. The location of "thereto" is not clear. The identity of the entities subject to "attached" is not clear.

In claims 1 and 14, the recitation of "dissociated first binding species" is indefinite because the identity of "dissociated" members is not clear. Whether said "first binding species" is dissociated from "a second substrate" and/or "binding regions" and/or "binding partners" is not clear.

In claims 1 and 14, the recitation of "the signal strength" lacks antecedent basis.

In claims 1 and 14, the recitation of "detrimentally affecting" lacks antecedent causal basis. The cause(s) of said detrimental effect is not clear.

In claim 12, the recitation of "regions adapted to selectively bind" is indefinite because the mechanism by which a "region" can bind a binding species is not clear. The physical parameter(s) belonging to said "regions" that is/are modified is not clear. The structure(s) corresponding to said adaptation.

In claim 14, the recitation of "regions capable of selectively binding" is indefinite because the mechanism by which a "region" can bind a binding species is not clear. The physical parameter(s) belonging to said "regions" that provide capability is/are not clear.

***Claim Rejections - 35 USC § 102***

Claims 1-8, 12 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman et al. (US 6,406,913).

Ullman et al. teach a reagent comprising a fluid medium (see col. 36, lines 1-32) containing a first substrate (see col. 19, lines 47-65) having a first binding species (see col. 14, lines 55-67) attached thereto (see col. 19, lines 66-67), said first binding species capable of dissociating from the first substrate (see col. 20, line 8, "non-covalent interactions"); and a second substrate having binding regions having binding partners capable of selectively binding said first binding species (see col. 35, lines 36-38, see col. 37, lines 28-35). The language "without detrimentally affecting the signal strength of said assay" does not structurally differentiate Applicants' invention from the reagent of Ullman et al. because Examiner considers such language as functional in nature. See MPEP 2114.

With respect to claims 2-3 and 15-16, Ullman et al. teach a reagent wherein the first substrate and second substrates are the same material or different material (see col. 21, lines 23-35).

With respect to claim 7, Ullman et al. teach a reagent comprising a non-porous material (see col. 19, lines 47-48) including an outer surface porous to binding species (see col. 21, lines 23-25, "dissolve in"; col. 22, lines 8-9, "incorporated into") and an inner surface having an affinity for said binding species (see col. 15, lines 38-40).

With respect to claim 12, Ullman et al. teach a reagent used in a sandwich type assay (see col. 35, lines 25-33) comprising a first binding species (see col. 37, lines 58+, "TSH"), wherein a first portion (see col. 38, lines 7-9) is attached to the first substrate and a second portion is dissociated from the first substrate, and the second portion binds to a second substrate.

Art Unit: 1641

With respect to claim 14, Ullman et al. teach a reagent wherein specific binding pair members are located on the surface (see col. 14, lines 55-56) of different supports (see col. 19, lines 47-65) and are used in a competitive assay format (see col. 35, lines 36-38, see col. 37, lines 28-35) wherein one binding member is complementary to the other binding member (see col. 37, lines 28-35).

***Response to Arguments***

In prior Office Action, Table 1-6 were objected to because the identity of “[I]level” or exact quantity or unit of measurement of the various “[I]level” was not clear. In response, Applicants argue that the term “Level” is adequately clear as used in the specification and in light of common knowledge to those reasonably skilled in the art. Applicants’ argument is not persuasive because the specification does not appear to adequately define the term “Level”. In what context, field, or discipline the term “Level” is common knowledge is not clear. Additional clarification is requested.

In prior Office Action, claims 12 and 14 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the mechanism by which a “region” binds a binding species is not clear. In response, Applicants argue that the specification is replete with examples of how a “region” binds a binding species in paragraphs [0019], [0023], [0024], [0032] and [0036]. Applicants’ argument is not persuasive because paragraphs [0019], [0023], [0024], [0032] and [0036] do not recite the term “region” or describe a mechanism by which a “region” binds a binding species.

In prior Office Action, claims 1-8, 12 and 14-16 were rejected under 35 U.S.C. 102(b) as being anticipated by Ullman et al. (US 6,406,913). In response, Applicants attempt to distinguish Applicants’ invention from the teachings of Ullman et al. by amending claims 1 and 14 to add the limitation of binding partners “capable of selectively binding dissociated first binding species without detrimentally affecting the signal strength of the assay” (see Applicants’ reply, p. 8, fourth full paragraph). Applicants’ argument has been carefully considered but is not persuasive. As stated supra, *Claim Rejections - 35 USC § 102*, the language “without detrimentally affecting the signal strength of said assay” does not structurally differentiate Applicants’ invention from the reagent of Ullman et al. because Examiner considers such language as functional in nature. See MPEP 2114. As stated in the prior Office Action, Ullman et al. describe a second binding partner capable of selectively binding a first binding partner (see col. 35, lines

Art Unit: 1641

36-38, see col. 37, lines 28-35). Thus, Ullman et al. appear to describe every structural limitation of claim 1.

In addition, Applicants appear to argue that while Ullman et al. describe cavities on the binding species, Ullman et al. do not teach a permeable (porous) material, as recited in claim 7. This argument is not persuasive because the plain language of claim 7, as amended, does not appear to require said "material" to be permeable (porous). Instead, claim 7 appears to require said "material" to be "non-porous".

In addition, Applicants traverse Examiner's rejection of claim 12 by claiming an inability to locate in Ullman et al. "where it is disclosed that a second portion of the first binding species is dissociated from the first substrate and then binds to a second substrate" (see Applicants' reply, p. 8, last paragraph). This argument is not persuasive because Ullman et al. describe a second portion of the first binding species (see col. 38, line 9, " $\beta$ -subunit") that is dissociated from the first substrate (see col. 38, lines 7-9, "[o]ne antibody recognizes the  $\alpha$ -subunit") and then binds to a second substrate (see col. 38, lines 7-9, "the other recognizes the  $\beta$ -subunit").

Art Unit: 1641

***Conclusion***

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Vinci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Vinci  
Examiner  
Art Unit 1641

djv

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*6/17/05*